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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,383	10/10/2000	Gertrud Hotten	2923-120	7142

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/684,383

Applicant(s)
Hotten et al.

Examiner
Prema Mertz

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 3, 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-34 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

1. Amended claims 24-26, original claims 27-28 and new claims 29-34 (Paper No. 15, 4/3/03), are under consideration.
2. Receipt of applicant's arguments and amendments filed in Paper No. 15 (4/3/03) is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 15, 4/3/03:
 - (i) the objections to the specification;
 - (ii) the rejection of claim 24 under 35 U.S.C. 102(b) as being anticipated by Forage et al. (1986) and
 - (iii) the rejection of claims 24, 27, under 35 U.S.C. 102(b) as being anticipated by Mason et al. (U.S. Patent No. 4,798,885).
4. Applicant's arguments filed in Paper No. 15 (4/3/03), have been fully considered but were persuasive in part. The issues remaining as well as new issues are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, first paragraph

6. Claims 24-28, 29-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey

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to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record set forth at pages 3-10 of the previous Office action (Paper No. 9, 10/21/02).

Applicants argue that the human protein begins between amino acid 217 and 240 and the mouse protein also starts between amino acid 217 and 240. However, contrary to Applicants arguments, Applicants are arguing that it is expected that amino acids can be missing at the N-terminus of MP121 as long as the protein folds correctly and the mature protein contains the conserved cysteine residues. This argument is irrelevant because it does not disclose where the mature MP121 protein specifically begins. Applicants also argue that the specification defines the term "mature protein" to encompass functional partial regions which exhibit "essentially" the same biological activity, which definition is itself inadequate to fulfill the requirements of 35 USC 112, first paragraph. Furthermore, the scope of the term "essentially" is very broad and therefore the biological activity cannot be ascertained.

Applicants argue that claim 24 has been amended to recite "containing seven conserved cysteine residues". However, contrary to Applicants arguments the scope of this term is very broad because the claim fails to recite where the cysteine residues are located. If Applicants will kindly review page 1404 of In re Wands, they will find that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or

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absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Given the breadth of claim 24, in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of skill in the art to practice the claimed invention.

New claim 29 recites "conservative amino acid substitutions" of SEQ ID NO:2, SEQ ID NO:4 or the mature parts thereof. The instant specification fails to disclose which amino acids in the instantly claimed proteins which are required for activity and those that are not required. There is not adequate guidance as to the nature of protein active analogues that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Even if the active residues were identified in the specification as indeed essential for protein function, they would not be sufficient, as the ordinary artisan would immediately recognize that an active site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. It is deemed that to make each of the possible amino acid replacements for each of the non-essential residues, even if only conservative replacements were made, would constitute undue experimentation. The introduction of non-conservative substitution (s), non-naturally occurring amino acids, deletions or insertions further

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raises the possible number of species. Therefore, applicants have not presented enablement commensurate in scope with the claims.

Claim Rejections - 35 USC § 112, second paragraph

7. Claims 24-34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24, lines 5-6, 8-9, is vague and indefinite because it recites nucleotide fragments but it is unclear in which SEQ ID NO: these nucleotide fragments are located.

In claim 29, line 3, there is no antecedent basis for the limitation "the" mature protein.

In claim 29, line 5, there is no antecedent basis for "the seven cysteine residues".

Regarding claim 29, lines 3-4, the phrase "includes" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP.. § 2173.05(d).

In claims 24 and 29, the metes and bounds of "seven conserved cysteine residues" and "seven cysteine residues" is unclear. Are these cysteine residues contiguous or if not where are their specific locations in the protein molecule.

Claim 30 is rejected as vague and indefinite for reciting BMP because the full meaning of the acronym "BMP" should be stated at its first use in any independent claim.

Claims 25-28 and 31-34 are rejected as vague and indefinite insofar as they depend on the above claims for their limitations.

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Conclusion

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.


Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Prema Mertz Ph.D.
Primary Examiner
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May 13, 2003